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| 10/697,862 | 10/30/2003 | Jason A. Demers | 1062/D84 | 9749 |
| 73544 | 7590 | 02/06/2009 | | |
| Michelle Saquet Temple DEKA Research & Development Corporation 340 Commercial Street Manchester, NH 03101-1129 | | | EXAMINER | |
| | | | DEAK, LESLIE R | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/697,862 | Applicant(s) DEMERS ET AL. |
| | Examiner LESLIE R. DEAK | Art Unit 3761 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 March 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-73 is/are pending in the application.
 - 4a) Of the above claim(s) 49-60 and 67-69 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-48,61-66 and 70-73 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/1449/0C)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8, 11, 15-18, 20-24, 25-32, 35, 39-41, 42, 44-47, 61, 62, 63, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al.

In the specification and figures, Kramer discloses the apparatus substantially as claimed by applicant.

With regard to claims 1, 2, 4, 5, 61, Kramer discloses a pump cassette 10 for use with a pump 42, wherein the cassette includes at least one pump chamber 44, and a first inlet port 22 in communication with the pump chamber 44 (see FIGS 1-2 and accompanying text).

Kramer fails to disclose a mechanically driven spiking assembly, but does disclose that the cassette is connected to at least a first container C with a cover via tubing lines S. Bloom discloses an automated vial loading method and apparatus for administering medicament to a patient. The apparatus comprises a cassette and a mechanically operated spiking assembly (vial loading assembly 200) comprising a spike 118 that is in fluid communication with the pump cassette and the pump chambers (see Bloom column 19). The mechanically operated assembly prevents accidental needle

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sticks to the operator and comprises a microprocessor-based controller that is capable of controlling the spiking and detecting incomplete spikes (see for example, column 12, lines 54-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a mechanically driven spiking assembly as disclosed by Bloom to the apparatus disclosed by Kramer in order to prevent accidental needle spikes with manual loading, as taught by Bloom.

With regard to claim 3, Bloom discloses that the connections between the cassette and the vials may be used to both inject and withdraw fluid from the vials 85, meeting the limitations of the claims (see Bloom column 16, lines 54-67).

With regard to claims 5, 6, and 30, spike housing comprises two substantially identical ring halves that are joined together to form a ring.

With regard to claims 7, 31, Bloom illustrates that the spike assembly comprises a spike housing (unlabeled, see FIGS 10, 13).

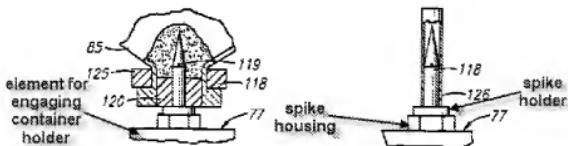
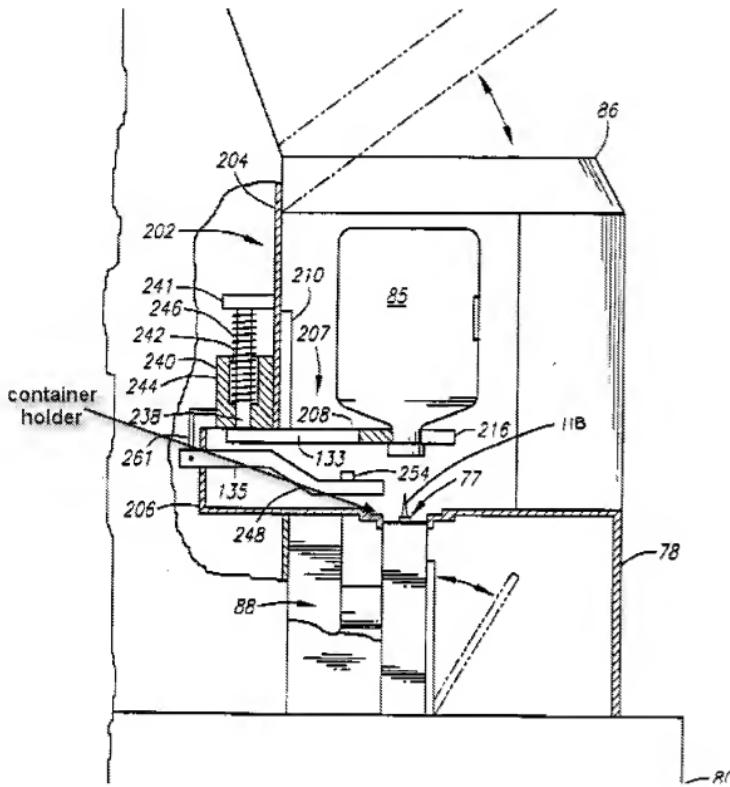


Fig. 9

Fig. 10

With regard to claims 8, 32, Bloom teaches that the spike assembly comprises a spike holder, but is silent as to the method of attachment. The claimed phrase "wherein the spike holder is overmolded onto the at least one spike" is being treated as a product by process limitation; that is, that the spike holder is overmolded onto the spike. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Bloom is silent as to the process used to attach the spike holder, it appears that the product in Bloom would be the same or similar as that claimed; especially since both applicant's product and the prior art product comprises a spike with a spike holder.

With regard to claims 15, 16, 39, 40 Bloom discloses that the housing 208 of the spike assembly comprises an element, top of cassette 77, that engages a container, surface 206. (See FIG 13, as annotated by the Examiner, below.)



With regard to claims 17, 18, 20-22, 25-29, 42, 44-46, 62, 63, 65, 66, both

Kramer and Bloom teach that the apparatus may comprise multiple spikes, containers, connecting tubing lines, and ports, suggesting the apparatus claimed by Applicant (see Kramer FIG 2, Bloom FIGS 5A, 8).

With regard to claims 23, 24, 47, 48 Bloom discloses that the cassette may comprise two fluid chambers 109, 110, that may be programmed to operate as claimed, wherein the cassette is pneumatically operated by pump 88 (see Bloom column 16, lines 47-53, column 15, lines 34-36).

With regard to claims 11 and 35, Bloom discloses that the apparatus may comprise a spike guard or cap 126 (see FIG 10 and accompanying text).

With regard to claims 71 and 73, Bloom discloses that the fluid delivery module or bladder 88 pneumatically operates cassette 77 (see column 13, lines 54-67).

3. Claims 9, 10, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 4,111,469 to Kavick .

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 9, 10, 33, and 34, the cited prior art fails to teach a barb on the tubing holder to retain a tube in place and an element on the housing to retain the tube in place. However, Kavick discloses a device for connecting fluid conduits with a pointed stem connected to a holder 23, inside a housing 16, wherein the holder and stem comprise barbs 26 and the housing comprises spikes 12 to retain an inserted tube 21 in place. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add retaining means to a housing and a holder as taught by Kavick, in the assembly suggested by the cited prior art, in order to sandwich a tubing member between retaining elements to secure it in place.

4. Claims 12-14, 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 6,159,192 to Fowles et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 12, 13, 36, and 37, the cited prior art fails to teach a spike guard with a grommet capable of being pierced by the spike wherein the grommet may function as a fluid seal when in contact with a container. Fowles teaches a medical connector apparatus comprising a spike 37, spike guard 106 with a pierceable membrane or grommet at the end of the guard 106 (see FIG 4). When engaged with a container, the grommet may scrunch up and seal against the spike housing, creating a fluid seal (see FIG 3).

With regard to claims 14 and 38, the spike assembly disclosed by Fowles comprises sleeves that protect the spike from inadvertent needle operator intrusion, wherein the sleeves have locking ribs that may be engaged to lock the sleeves in a particular position, and then disengaged to move the sleeves to another position (see column 7, lines 25-46). Accordingly, it is the position of the Examiner that the locking mechanism claimed by applicant is suggested in the prior art. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the fluid mixing and injection assembly with spike as suggested by the cited prior art with a spike guard with tabs as disclosed by Fowles, to enable the guard to be moved from a protecting position to an engaged position, as taught by Fowles.

5. Claims 19, 43, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 5,116,316 to Sertic et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 19, 43, and 64, the cited prior art fails to teach a filter within a flow path. Seric teaches an automatic in-line reconstitution and delivery system comprising a filter 81 between vial 42 and the delivery system (see column 9, lines 40-48) in order to prevent particulate matter from being administered to the patient. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to add a filter as disclosed by Sertic to the cassette and spiking assembly suggested by the cited prior art in order to prevent undissolved particulate matter from being administered to the patient.

6. Claims 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 5,334,178 to Haber et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejection above) with the exception of a silicone container cover. Kramer and Bloom use standard medicament vials, which are well-known in the art to comprise septums that may be formed of silicone, as illustrated by Haber (see column 4, line 65 to column 5, line 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use silicone as

disclosed by Haber as the vial cover for the vial suggested by the prior art, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

Response to Arguments

7. Applicant's arguments filed 18 December 2008 have been fully considered but they are not persuasive. Applicant argues that the prior art references do not disclose or suggest the claimed apparatus by reciting the claim limitations. It is the position of the Examiner that absent any specific argument pointing out the shortcomings in the combination suggested by the prior art, the cited prior art reasonably suggests the limitations of the claimed invention.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
4 February 2009